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09/537,118	03/29/2000	Harry Dugger III	PHCO3.0-008	7521

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PENNIE & EDMONDS LLP
1667 K STREET NW
SUITE 1000
WASHINGTON, DC 20006

EXAMINER	
HAGHIGHATIAN, MINA	

ART UNIT	PAPER NUMBER
1616	24

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/537,118	Applicant(s) DUGGER, HARRY	
	Examiner Mina Haghighatian	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *26-38,53-61 and 79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *26-38, 53-61 and 79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed August 08, 2003 was entered. No new claims added and no claims deleted.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 26, 30, 33, 37, 53, 56, 58-60 and 79 rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719197).

Kanios teaches compositions and methods for topical administration of pharmaceutically active agents. Topical administration means a direct contact of the formulation with tissue, such as skin or membrane, particularly the oral or **buccal mucosa** (col. 1, lines 29-59).

Kanios discloses that the composition comprises a therapeutically effective amount of at least one pharmaceutically active agent, a pharmaceutically acceptable solvent for the active agent (col. 2, lines 22-28). The solvent is preferably a polyhydric alcohol such as polypropylene glycol, ethylene glycol, also solvents such as fatty acids such as oleic acid, as well as fatty esters or alcohols. The solvent is present in an amount from about 20 to 50 weight percent based on the total weight of the composition (col. 4, lines 1-49). The concentration of the solubilized active agent can range from 1 and 50% by weight (col. 8, lines 1-9). The acceptable carrier is intended to be any

suitable finite or non-finite carrier including liquids, semi-liquids or solid carriers. Thus the active agent may be admixed with carriers such as spray-solution or any non-finite carrier known in the art for delivery of active agents (col. 8, lines 54-67). Other additives may be incorporated into the formulations such as flavorings (col. 10, lines 48-56).

Kanios discloses that pharmaceutically active agents suitable for such formulation include narcotic analgesics, hormones, antihistamines, antibiotics such as erythromycin, antinauseants such as ondansetron, antiulceratives such as cimetidine, immunosuppressants such as cyclosporine, benzodiazepines, clozepaine, etc (cols. 12-31).

Kanios does not exemplify a buccal spray formulation, however it does clearly teach that the formulations may be in the form of a spray solution for administering to the oral mucosa and thus to one of ordinary skill in the art, forming a buccal spray containing an active agent and a solvent, would be a logical extension of the disclosure of Kanios.

Claim 27-29, 31-32, 34, 38, 54-55, 57 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al (5,719,197) as applied to claims 26, 30, 33, 37, 53, 56, 58-60 and 79 above, and further in view of Singer et al (5,364,616).

Kanios, discussed above, lacks specific disclosure on the concentration range and examples of the flavoring agent.

Singer teaches methods for prevention or treatment of gingivitis or periodontitis comprising topical administration to oral cavity, a composition comprising a safe and effective amount of a selective histamine-2 receptor antagonist compound, and oral care compositions used thereof. Compositions comprise about 0.001 to about 20% of a H-2 antagonist such as cimetidine, about 2 to about 99% of an oral carrier and about 0.04 to about 2% of flavoring agent by weight. The suitable carriers include ethanol, water and polyhydric alcohols such as glycerin, polyethylene glycol and propylene glycol. Suitable flavoring agents include menthol, oil of wintergreen, oil of peppermint, oil of clove, etc (col. 15-17).

Singer discloses that the said compositions, suitably in the form of a mouthspray, may optionally include other ingredients such as other active agents including antibiotics, anti-inflammatories, vitamins and minerals (col. 18-19).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made, given the general teachings on the topical (oral) spray formulations of Kanios to look in the art for relative and suitable concentration range and examples of the flavoring agent with the reasonable expectations of preparing an oral formulation that is acceptable and tolerable by patients, since flavoring is an important aspect of oral formulations.

Double Pat nting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9 and 10 of U.S. Application No. 10/100,156 (allowed, not yet issued). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 35 and 36 are generic to all that is recited in claims 9-10 of U.S. Application No. 10/100,156. That is, claims 9 and 10 of U.S. Application No. 10/100,156 fall entirely within the scope of claims 35 and 36, or in the other words, claims 35 and 36 are anticipated by claims 9 and 10 of U.S. Application No. 10/100,156. Specifically, the formulation of claim 9 of the U.S. Application No. 10/100,156 is the formulation of claim 35 of the instant application and claim 10 of the U.S. Application No. 10/100,156 is the formulation of claim 36 of the instant application.

Response to Arguments

Applicant's arguments filed August 08, 2003 have been fully considered but they are not persuasive. However due to the amendments filed, the rejection of claims under 102(b) over Kanios and Singer are withdrawn.

Applicant argues that Kanios is teaching compositions and methods for the topical administration of active agents to a mammal, in particular, anesthesia and local anesthetic agents. Applicant stresses that Kanios "merely discloses compositions that are applied topically and have local effect, such as local anesthetic". This is not correct, because while Kanios is concentrating to some extent on local anesthetic agents, it is clearly disclosing administering to oral mucosa as well. Furthermore, it is stated that preferred embodiments do not teach away from a broader disclosure. See *In re Susi*.

Kanios is also listing many different active agents suitable for the said formulation. Obviously Kanios did not imply that all of the listed medications will be for local effect. It is further noted that the instant claims are "composition" claims, and the product's properties are considered inherent. Therefor if Kanios is disclosing a formulation containing the same ingredients as the instant claims are reciting, then it is taken that both formulations will be absorbed systemically once administered to the oral mucosa. It is also noted that "for transmucosal absorption" is considered intended use and is not given weight during examination.

Kanios, therefor, teaches the formulations and the method of administration.

With regards to Singer's reference, Applicant argues that "clearly to treat gingivitis or peridontitis one would want the composition to remain in the oral cavity and

not to be delivered to the systemic circulatory system". This is not commensurate with scope of instant claims. The instant claims are drawn to compositions containing an active, a solvent and a flavoring agent. Singer is disclosing the same formulations and they are formulated in a spray solution form administered to the oral cavity. Therefore the reference meets the requirement of the instant claims.

Applicant argues that "there is no disclosure or suggestion in either Kanios or Singer of a composition applied to the oral mucosa that provides an active compound to the systemic circulatory system or any disclosure on how to get a systemic effect". Again this is not commensurate with the scope of the instant claims. Kanios is clearly teaching a spray solution formulation containing an active, a solvent and an additive such as flavoring agent, which may be administered to the oral mucosa. Singer is teaching formulations in a spray solution form which include an active, a solvent and a flavoring agent such as oil of peppermint, and discloses suitable concentration ranges for the flavoring agents. Clearly one of ordinary skill in the art, given the formulations of Kanios would be motivated to look in the art for specific flavoring agents and a suitable concentration range because both formulations are sprayed in the oral cavity and flavor in such formulations is an important factor in patient compliance.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
October 1, 2003

MICHAEL G. HARTLEY
PRIMARY EXAMINER